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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,845	03/12/2004	Rong-Ming Ho	UCL0301	8486

22192 7590 10/19/2005

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EXAMINER

MULLIS, JEFFREY C

ART UNIT	PAPER NUMBER
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1711

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/799,845

Applicant(s)

HO ET AL.

Examiner

Jeffrey C. Mullis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18, 21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18, 21 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

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Applicants have failed to place a proper claim for domestic priority in the first sentence of the specification.

Claims 1-18, 21 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as filed discloses nothing about how to produce block copolymers having a plurality of first polymer blocks and a plurality of second polymer blocks and in fact refers to diblock copolymers and are therefore not enabled and fail to provide a written description .

Claims 1-18, 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The "said objected" in claim 10 lack antecedent basis within this claim.

It is not clear what applicants intent by a plurality of first and second blocks given that applicants specification specifically refers to diblocks copolymers, ie materials with only one first and one second block.

Applicants usage of the term "chiral" is unclear given that chirality as viewed in the art is by definition a molecule (or object) with a non super imposable mirror image while applicants remarks appear to indicate that by "chiral" applicants

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intend a mixture (possibly chemically combined as a block) of monomers of opposite chirality.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by Zalusky et al. JACS, 2001 ,123,1519-1520.

Zalusky discloses a block copolymer containing polystyrene blocks and a block containing mixtures of D and L lactic acid residues (chiral units).. Note Figure 2 for a SEM of the material after hydrolysis (a process leaving voids where the lactic acid residue containing block microdomains were) showing voids

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at far under 100 nm and thus the block copolymer had nanoscale microstructures in the form of microdomains prior to hydrolysis.

Claims 21 and 22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Choi et al. (US 6,210,717).

Choi et al. In Examples 1 and 2 disclose a block copolymer having L-lactic residues as one block. As block copolymers generally exhibit microphase separation, formation of microstructures in the form of microdomains would be inherent in the block copolymer production process. With regard to applicants' remaining characteristics, all features of the polymer of the claims are present explicitly except for characteristics and applicants' characteristics are therefore presumed inherent.

When the reference discloses all the limitations of a claim except a property or function, and the Examiner cannot determine whether or not the reference inherently possesses properties which anticipate or render obvious the claimed invention, basis exists for shifting the burden of proof to applicant. Note In re Fitzgerald et al. 619 F. 2d 67, 70, 205 USPQ 594, 596, (CCPA 1980). See MPEP § 2112-2112.02.

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Claims 21 and 22 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Park et al. (US 6,517,869).

Park et al. In Example 7 disclose a block copolymer having L-lactic residues as one block. As block copolymers generally exhibit microphase separation, formation of microstructures in the form of microdomains would be inherent in the block copolymer production process. With regard to applicants' remaining characteristics, all features of the polymer of the claims are present explicitly except for characteristics and applicants' characteristics are therefore presumed inherent.

When the reference discloses all the limitations of a claim except a property or function, and the Examiner cannot determine whether or not the reference inherently possesses properties which anticipate or render obvious the claimed invention, basis exists for shifting the burden of proof to applicant. Note In re Fitzgerald et al. 619 F. 2d 67, 70, 205 USPQ 594, 596, (CCPA 1980). See MPEP § 2112-2112.02.

Claims 1-6 9-18 21 and 22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kim et al. Polymer Preprints 1998, 39 (2), 423-424.

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Kim et al discloses the production of polystyrene-poly-L-lactide. As the structure of the block copolymer of the claims and application are identical, identical characteristics are assumed inherent and isolation of the block copolymer would presumably cause microphase separation.

With re to applicants product by process claim both applicants and patentees produce poly-L-lactide-polystyrene diblock copolymer and both would therefore inherently appear to be the same.

Product-by-process claims are not rejected using the approach set out in Graham v. Deere. It is applicant's burden to show that there is a non-obvious difference between the product of a product-by-process claim and a prior art product which reasonably appears to be the same or only slightly different whether or not the prior art product is produced in the same manner as the claimed product. Note In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972) and In re Thorpe, 227 USPQ 964 (CAFC 1985) in this regard.

When the reference discloses all the limitations of a claim except a property or function, and the Examiner cannot determine whether or not the reference inherently possesses properties which anticipate or render obvious the claimed invention, basis exists for shifting the burden of proof to applicant. Note

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In re Fitzgerald et al. 619 F. 2d 67, 70, 205 USPQ 594, 596, (CCPA 1980). See MPEP § 2112-2112.02.

Claims 21 and 22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Spinu, Journal of Macromolecular Science A33(10), p 1497-1530 (1996).

Page 1500-1503 disclose numerous examples of L-lactide-polystyrene block copolymers and as applicants specification discloses use of enantiomerically enriched monomers to produce at least one of their blocks it is assumed that applicants characteristics are inherent in the reference. Furthermore it is known in the art that in general polymer compatibility is the exception rather than the rule and for this reason only it is assumed that phase preparation of the various blocks takes place in the solid compositions.

When the reference discloses all the limitations of a claim except a property or function, and the Examiner cannot determine whether or not the reference inherently possesses properties which anticipate or render obvious the claimed invention, basis exists for shifting the burden of proof to applicant. Note In re Fitzgerald et al. 619 F. 2d 67, 70, 205 USPQ 594, 596, (CCPA 1980). See MPEP § 2112-2112.02.

Claims 21 and 22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Stevels et al. Macromolecular Chemistry and Physics, 196(11), p 3687-94 (1995).



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Stevens discloses stereoblock copolymers containing blocks of polymerized pure lactide enantiomer (abstract) and as applicants specification discloses use of enantiomerically enriched monomers to produce at least one of their blocks it is assumed that applicants characteristics are inherent in the reference.

Furthermore it is known in the art that in general polymer compatibility is the exception rather than the rule and for this reason only it is assumed that phase preparation of the various blocks takes place in the solid compositions.

When the reference discloses all the limitations of a claim except a property or function, and the Examiner cannot determine whether or not the reference inherently possesses properties which anticipate or render obvious the claimed invention, basis exists for shifting the burden of proof to applicant. Note In re Fitzgerald et al. 619 F. 2d 67, 70, 205 USPQ 594, 596, (CCPA 1980). See MPEP § 2112-2112.02.

Claims 21 and 22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Brizzolara et al. Journal of Computer Aided Materials design (1996) 3(1-3), p 341-350.

The authors disclose production of +PLA-PEG (see "Materials" on page 343) ) and as applicants specification discloses use of enantiomerically enriched monomers to produce at least one of their blocks it is assumed that applicants characteristics are inherent in the reference. Furthermore it is known in the art that in general polymer compatibility is the exception rather than the rule and for

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this reason only it is assumed that phase preparation of the various blocks takes place in the solid compositions.

When the reference discloses all the limitations of a claim except a property or function, and the Examiner cannot determine whether or not the reference inherently possesses properties which anticipate or render obvious the claimed invention, basis exists for shifting the burden of proof to applicant. Note In re Fitzgerald et al. 619 F. 2d 67, 70, 205 USPQ 594, 596, (CCPA 1980). See MPEP § 2112-2112.02.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-18, 21 and 22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 10/850169. Although the conflicting claims are not identical, they are not patentably distinct from each other because applicants claims do not exclude the various features of the copending claims such as forming a template.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed 8-3-05 have been fully considered but they are not persuasive. A polymer formed from chiral units is chiral even when formed from an equimolar mixture of R and S molecules. Lactic acid polymeric chains are not of such a nature that chirality is cancelled such as in a meso molecule and for this reason applicants characteristics appear inherent. A mixture which contains an equimolar mixture of D and L is racemic by definition. In fact the term Chiral does not pertain to mixtures at all. Applicants may mean that their block copolymers have the characteristic of being nanohelical due to use of enantiomerically pure monomers for formation of the blocks of their block copolymers. If so clarification and proof of such is required.

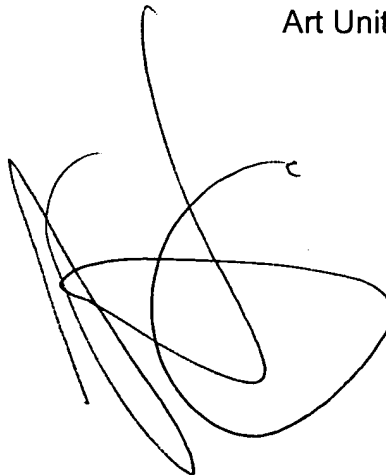
This Office action is not being made FINAL.

Any inquiry concerning this communication should be directed to Jeffrey C. Mullis at telephone number 571 272 1075.

JCM

2-28-05

Jeffrey C. Mullis  
J Mullis  
Art Unit 1711



**Jeffrey Mullis**  
**Primary Examiner**  
**Art Unit 1711**